K123748

Section 5. 510(k) Summary

MAY 0 7 2013

1. Administrative

Device Information

Device Name:	ABL90 Flex
Common Name:	Blood gases and blood pH test system
Product Code:	CHL (JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX)
Registration Number:	21 CFR 862.1120
Classification:	Class II
Classification Panel:	Clinical Chemistry

Submitter

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2. Description of Device Modification

The ABL90 FLEX is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO2 , pCO2, potassium, sodium, calcium, chloride, glucose, lactate, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF).

The change consists of an update to the Intralipid correction algorithm for Oxi parameters. The purpose of this update is to improve the suppression of Intralipid interference.

3. Intended Use

The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order.

4. Substantial Equivalence

The ABL90 FLEX with the Improved Intralipid correction algorithm for Oxi parameters is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
K111897 ABL90 Flex, Radiometer Medical ApS

Special 510(k):
ABL90 Flex - Improved Intralipid correction algorithm for Oxi parameters

Similarities		
Issue	**SE Device**	**Predicate Device (K111897)**
Intended Use	Same	The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.
Blood Gas Measurement	Same	pH, pO_2, pCO_2 by potentiometry
Electrolyte Measurement	Same	cK^+, cNa^+, cCa^{2+}, cCl^- by potentiometry
Metabolite Measurement	Same	cGlu, cLac by amperometry
Oximetry Measurement	Same	ctHb, sO_2, FO_2Hb, FHHb, FCOHb, FMetHb, FHbF by spectrophotometry
Performance Characteristics	Same	Identical Performance Characteristics
Calibration	Same	Two-Point liquid calibration
User Interface	Same	Menu driven touch screen
Software operating system	Same	Microsoft XPE
Sample Introduction	Same	Aspiration
Dimensions (height x width x depth)	Same	17.7 x 9.8 x 11.4 in
Weight	Same	11.1 kg
Ethernet	Same	1 × RJ45 connector, 100Base-Tx Fast Ethernet
USB	Same	Three connectors for USB port

Differences		
Issue	**SE Device**	**Predicate Device (K111897)**
Software version	Software version 2.6 MR4	Software version 2.5 MR2
Intralipid correction algorithm for Oxi parameters	Improved Intralipid correction algorithm for Oxi parameters implemented in Software version 2.6 MR4.	-

5. Performance Data

No performance characteristics are affected by the change. The performance data submitted in the original submission (k092686) still apply except the interference effect from intralipid to oximetry parameters was further reduced. The Reference Manual was updated to reflect the interference changes from intralipid to oximetry parameters.

6. Summary of Design Control activities

Risk Assessment

We conducted an FMEA risk analysis and mitigated all identified hazards to As Low As Reasonably Practicable (ALARP) per ISO-14971, and verified software mitigations by using test protocols. Results met predefined acceptance criteria

Performance testing:

Issue	Acceptance criteria	Verification method	Result and Pass/fail	Comments
Interference	Clinically relevant interferences must be known and specified in the labeling.	Verification study according to EP17-A2	Interferences have been determined and specified in the Reference Manual Pass	
Method comparison	Method comparison claims must be unchanged, i.e. 95% confidence intervals for the new algorithm must contain part of the predicted bias intervals for the old algorithm at the medical decision points as per EP9-A2.	In-house method comparison study vs. previous algorithm according to EP9-A2 with between 76 and 282 samples per parameter spanning the measuring range. Between 9 and 25% of the samples had elevated intralipid index values.	95% confidence intervals for the new algorithm contain part of the predicted bias intervals for the old algorithm at the medical decision points. Pass.	Existing method comparison claims still valid

Special 510(k):
ABL90 Flex - Improved Intralipid correction algorithm for Oxi parameters

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Issue	**Acceptance criteria**				**Verification method**	**Result and Pass/fail**				**Comments**
Method comparison		Slope	Intercept	r	In-house method comparison study vs. previous algorithm according to EP9-A2 with between 76 and 282 samples per parameter spanning the measuring range. Between 9 and 25% of the samples had elevated intralipid index values.		Slope	Intercept	r	Existing method comparison claims still valid
	*c*tHb	0.9-1.1	<±0.5g/dL	>0.975		*c*tHb	1.00	-0.10 g/dL	1.00	
	sO_2	0.9-1.1	<±1%	>0.975		sO_2	1.00	0.08%	1.00	
	*F*COHb	0.9-1.1	<±1%	>0.975		*F*COHb	1.00	-0.35%	1.00	
	*F*MetHb	0.9-1.1	<±1%	>0.975		*F*MetHb	1.00	-0.26%	1.00	
	FO_2Hb	0.9-1.1	<±1%	>0.975		FO_2Hb	1.00	0.28%	1.00	
	*F*HHb	0.9-1.1	<±1%	>0.975		*F*HHb	1.00	-0.02%	1.00	
	*F*HbF	0.85-1.15	<±5%	>0.85		*F*HbF	0.87	-4.24%	0.89	
LoQ	LoQ claims must be unchanged.				Data analysis and recalculation of existing LoQ verification data.	LoQs fulfilled acceptance criteria and were not affected by the change. Pass.				Existing LoQ claims still valid

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ABL90 Flex - Improved Intralipid correction algorithm for Oxi parameters

Issue	**Acceptance criteria**	**Verification method**	**Result and Pass/fail**	**Comments**
Bias and imprecision (S_0 and CV_x)	Claims for bias and imprecision obtained in-house must be unchanged, i.e. less than or equal to values specified in section 7 of the existing Reference Manual.	Data analysis and recalculation of existing performance verification data obtained in-house. Hypothesis H0: $\mu_{Improved} = \mu_{current}$ was tested statistically. Values for samples exceeding the index value initiating the new correction were recalculated and bias and imprecision were recalculated based on this and compared with the existing claims.	0.56% of measurements affected. In no case was the significance level α below 30% (typically >80%). The α acceptance level is ≥5%. This implies equal series mean for current and improved Intralipid algorithm for all the Oxi parameters. Recalculation verified that the acceptance criteria were met. Pass	Existing claims for bias and imprecision obtained in-house are still valid

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Issue	Acceptance criteria	Verification method	Result and Pass/fail	Comments
Linearity	Linearity claims must be unchanged, ie. the deviations from linearity must be less than or equal to existing claims.	Values for samples exceeding the index value initiating the new correction were recalculated and deviations from linearity were recalculated based on this and compared with the existing claims.	Recalculation verified that the acceptance criteria were met. Pass	Existing linearity claims still valid

7. Conclusion

The ABL90 FLEX with the improved Intralipid algorithm described above is substantially equivalent in Intended Use, fundamental scientific technology, and characteristics to the predicate ABL90 Flex (K111897). For the implementation of the change design control principles (risk management, verification and validation) have been applied which indicated that the change is of no impact to the performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2013

Radiometer Medical ApS
C/O Søren Bøgestrand
Akandevej 21
2700 Brønshøj
DENMARK

Re: K123748
Trade/Device Name: ABL90 FLEX Analyzer
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO_2, PO_2) and blood pH test system
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX
Dated: April 04, 2013
Received: April 08, 2013

Dear Søren Bøgestrand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123748

Device Name: ABL90 FLEX Analyzer

Indications for Use:
The ABL90 FLEX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, and oximetry in heparinised whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order.

pH, pO_2 and pCO_2: pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa^+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration,inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa^{2+}): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Chloride (*c*Cl⁻): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (*c*Glu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (*c*tHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO_2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

***F*O_2Hb:** oxyhemoglobin as a fraction of total hemoglobin.

***F*COHb:** carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

***F*MetHb:** methemoglobin as a fraction of total hemoglobin.

***F*HHb:** reduced hemoglobin as a fraction of total hemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): FHbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

Prescription Use__X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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